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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,617	09/20/2005	Thomas Gostelow	0119/0047	8144

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EXAMINER	
LOPEZ, AMADEUS SEBASTIAN	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/549,617	GOSTELOW, THOMAS	
	Examiner	Art Unit	
	Amadeus S. Lopez	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. [1], a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

Specification

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of

electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

Or alternatively, Reference to a "Microfiche Appendix": See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in

37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(l) Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

3. The disclosure is objected to because of the following informalities:

The specification requires the addition of the following subheadings as outlined above including: background of the invention, summary of the invention, brief description of the drawings, etc.

There are numerous pages missing from the submitted specification. The pages included are pages 1, 3, and 5. Please resubmit a complete specification including all of the missing pages.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claim 3 is rejected under 35 U.S.C. 112, first paragraph**, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claim 3, it is stated that the seal (3) includes a fluid passage opening (34) at one end ABOVE the seal and extending out of the trachea via the opening (4). From Fig. 1, the examiner would like to point out that the fluid passage opening (34) is never above the seal (3) as claimed in claim 3, and the device would not be able to function as stated within the specification if the fluid passage opening were above the seal.

5. **Claim 7 is rejected under 35 U.S.C. 112, first paragraph**, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant claims that the annular ring includes a resilient foam. This limitation to the annular ring is never mentioned nor described within the specification of the application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 3889688 to Eamkaow.

7. **With regards to claim 1**, what is taught and shown by Eamkaow in Fig. 1 is a tracheostomy device including a tubular member (10) adapted to provide a gas passage into the trachea (16) through an opening (Fig. 1) in neck tissues and an external retainer (32) for retaining the tubular member with the external surface of the neck adjacent the opening, characterized in that the patient end of the tubular member terminates adjacent the internal end of the opening, and that the device includes an internal retainer (26) for retaining the tubular member with the internal surface of the trachea adjacent the opening.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6840242 to McCoy in view of US Patent No. 3889688 to Eamkaow**.

9. **With regards to claim 1,** what is taught and shown by McCoy in Figs. 1 and 2 is a tracheostomy device including a tubular member (45 and 46) adapted to provide a gas passage into the trachea through an opening in neck tissues (Fig. 1). What is not taught by McCoy is an external retainer for retaining the tubular member with the external surface of the neck adjacent the opening characterized in that the patient end of the tubular member terminates adjacent the internal end of the opening and the device includes an internal retainer for retaining the tubular member with the internal surface of the trachea adjacent the opening. What is taught by Eamkaow is a tracheostomy tube with an external retainer (32) for retaining the tubular member with the external surface of the neck adjacent the opening characterized in that the patient end of the tubular member terminates adjacent the internal end of the opening, and that the device includes an internal retainer (26) for retaining the tubular member with the

internal surface of the trachea adjacent the opening. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tracheostomy tube of McCoy to include an exterior and interior retaining means as that taught by Eamkaow because it is well known in the art that an exterior retaining means such as placing a plate 32 against the exterior surface of the user's neck adds much needed stability to the tracheostomy tube within the opening of the tube and prevents it from being dislodged; It would also have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tracheostomy tube of McCoy to include an interior retaining means such as that taught by Eamkaow because it is well known in the art that an interior retaining means would help prevent accidental ejection of the tracheostomy tube from the opening in the neck of a user when he/she sneezes or coughs.

10. **With regards to claim 2,** what is taught and shown by McCoy in Figs. 1-3 is a tracheostomy device characterized in that the device includes a seal (21; Fig. 2 and 3) for substantially sealing the trachea above the opening into the trachea (Fig. 1).

11. **With regards to claim 3,** what is taught and shown by McCoy in Figs. 1-3 is a tracheostomy device characterized in that the seal (21) includes a fluid passage opening (52) at one end below the seal (21) and extending out of the trachea via the opening. The examiner is assuming that what the applicant means to claim is that the fluid passage opening (34) is below the seal (3) as shown in Fig. 1.

12. **With regards to claim 4,** what is taught and shown by McCoy in Figs. 1-3 is a tracheostomy device characterized in that the fluid passage (48 and 52) is a suction passage (see abstract).

13. **With regards to claims 5 and 6,** what is taught and shown by McCoy in Figs. 1-3 is a tracheostomy device characterized in that the seal includes a deformable annular ring (21; In Col. 4, lines 8-60, McCoy states that the collection receptacle 21 is inflatable/deflatable and is therefore "deformable") arranged to engage the surface of the trachea (See Fig. 1 and 3 where it is shown that collection receptacle 21 is a ring and engages the wall of the trachea).

14. **With regards to claim 8,** what is taught and shown by McCoy in Figs. 1-3 is a tracheostomy device characterized in that the seal (21) includes a web (70) extending across the ring (See Fig. 3; Col. 5, lines 2-11; McCoy discloses that film 70 provides a soft and deformable cover for the collection receptacle which is designed so that the width or diameter of the collection receptacle 21 is such as to provide a seal within the trachea).

15. **With regards to claim 9,** what is taught and shown by McCoy in view of Eamkaow is a tracheostomy device with all the limitations of claim 1 as rejected above. Further what is not taught by McCoy is an external retainer in the shape of a flange and an internal retainer being a displaceable member. What is taught by Eamkaow is a tracheostomy device characterized in that the external retainer (32) is a flange (See Fig. 1 and 3) and that the internal retainer (26) is a displaceable member (Col. 3, lines 25-34 where it is stated that the balloon 26 is inserted and removed from the wall of the

passage in the deflated configuration; therefore the internal retaining means 26 is a displaceable member). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tracheostomy tube of McCoy to include a flange like exterior retaining means as taught by Eamkaow because it well known in the art that a flange like retaining means such as a plate shown in Fig. 3 is a good configuration to add much needed stability to the tracheostomy tube within the opening of the tube and prevents it from being dislodged by providing a flush surface against the exterior surface of the neck of the user. It would also have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tracheostomy tube of McCoy to include a displaceable member as the internal retaining means as taught by Eamkaow because a displaceable internal retaining means member is necessary for the removal of the tracheostomy device from within the opening in the neck of the user. If the internal retaining means were not displaceable, it would make it very difficult and even painful for the user to remove the tracheostomy device from the opening in their neck.

16. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over McCoy in view of Eamkaow as applied to claim 5 above, and further in view of US Patent No. 5638813 to Augustine.

17. **With regards to claim 7**, what is taught by McCoy in view of Eamkaow is a tracheostomy device with all the limitations of claim 7 with the exception of that the annular ring (21) includes a resilient foam. What is taught by Augustine is a tracheal tube with a self supporting tracheal tube cuff composed by one or more compressible,

resilient parts between the tracheal tube and the cuff. "Such parts may be, for example, compressible, annular foam plastic or form rubber disks or washers surrounding the tube within the cuff..." "The compressed foam disk create a static low pressure seal between the cuff and the tracheal wall, throughout the respiratory cycle." Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tracheostomy device of McCoy/Eamkaow to make the annular ring include a resilient foam because it is well known in the art as taught by Augustine that annular rings made of foam provide good low pressure seals between the cuff and the tracheal wall, throughout the respiratory cycle so that it as comfortable for the user as possible without causing much irritation.

18. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over US McCoy in view of Eamkaow as applied to claim 9 above, and further in view of US Patent No. 4516578 to Shuffield.

19. **With regards to claim 10,** what is taught and shown by McCoy in view of Eamkaow is a tracheostomy device with all the limitations of claim 9 as rejected above. Further what is not taught by McCoy is a displaceable member being a hinged tab, and that the tab is connected with a cord by which the tab can be displaced. What is taught by Eamkaow is a tracheostomy device characterized in that the displaceable member (26) is a hinged tab (From Fig. 1 it is shown that inflated balloon 26 acts as a hinged tab; it is hinged where it is attached to the tube 10). What is not taught by McCoy/Eamkaow is that the tab is connected with a cord by which the tab can be displaced. What is taught and shown by Shuffield in Fig. 7-10 is a device to be placed

within a body lumen (in this case the rectum) with an interior retaining means formed by the head portion retaining means, disc shaped diaphragm (14), that is attached to a pull cord (19). The diaphragm is flexible and resilient and is able to fold around the tube (11) as shown in Fig. 10 when the cord 19 is pulled for removal from the rectum of the user. What is taught by Shuffield is that "the most common technique is to utilize an inflatable balloon (such as 26 and 28 taught by Eamkaow) in the vicinity of that distal end. With the balloon deflated, the device is introduced into the anal opening. Then, after the balloon and the distal end are located inside the rectum the balloon is inflated so as to prevent removal thereof and to prevent the escape of the liquid, while carrying out the medical procedure (Col. 1, lines 18-25)... Hence it is a purpose of the present invention to provide a new and improved rectal device of the type (Col. 1, lines 56-62)... One such use is as an occluder (Col. 3, lines 5-11)..." The inflatable balloons taught by Eamkaow are used to occlude the opening within the neck of the user and provide a retaining means within the interior surface of the patient's neck. The device taught by Shuffield provides a new and improved means of occluding an opening within the body that provides a pull cord that allows the user to easily remove the device from the body orifice. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the inflatable balloon retaining means taught by Eamkaow for the pull cord diaphragm assembly interior retaining means since they both provide effective means for retaining a tube like device within an opening in the body of a user.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to the applicant's disclosure. US 5123922, US 4278081, US 6527737, US 4471782, US 5738654, and US 5056515.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amadeus S. Lopez whose telephone number is (571) 272-7937. The examiner can normally be reached on Mon-Fri 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amadeus S Lopez
Examiner
Art Unit 3743
June 08, 2006

ASL

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